UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte D. WADE WALKE,
YI HU, BORIS NEPOMNICHY,
C. ALEXANDER TURNER, JR. and BRIAN ZAMBROWICZ

Appeal No. 2005-2440
Application No. 09/783,320

ORDER UNDER 37 CFR § 41.50(d)

Before WILLIAM F. SMITH, ADAMS and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

ORDER UNDER 37 CFR § 41.50(d)

Under the provisions of 37 CFR § 41.50(d),[1] we require Appellants to address the following matters:

We invite attention to commonly assigned Application No. 09/714,882.[2] That application was the subject of an appeal to this board (Appeal No. 2004-1732), which was decided on September 24, 2004.

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[1] "The Board may order appellant to additionally brief any matter that the Board considers to be of assistance in reaching a reasoned decision on the pending appeal. Appellant will be given a non-extendable time period within which to respond to such an order." 37 CFR § 41.50(d).

[2] The named inventors in the instant application are D. Wade Walke, Yi Hu, Boris Nepomnichy, C. Alexander Turner, Jr. and Brian Zambrowicz. In Application No. 09/714,882, the inventors are C. Alexander Turner Jr., Michael C. Nehls, Glenn Friedrich, Brian Zambrowicz, and Arthur T. Sands.

The issues and arguments in Appeal No. 2004-1732 bear close resemblance to those in this appeal. In Appeal No. 2004-1732, the broadest independent claim (claim 2) was directed to "[a]n isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO:2." The polypeptide of SEQ ID NO:2 was disclosed to have sequence similarity to Notch receptor ligands, but the specification did not disclose the biological function of the putative ligand. The only issue in Appeal No. 2004-1732 was whether the specification disclosed a patentable utility for the claimed invention.

In Appeal No. 2004-1732, the appellants argued, among other things, that the claimed nucleic acids had utility because they could be used in methods that do not depend on the biological activity of the encoded protein. The appellants argued that the claimed nucleic acids were useful "in determining the genomic structure of the corresponding human chromosome . . ., for example mapping the protein encoding regions" and that they "are useful for functionally defining exon splice-junctions." Application No. 09/714,882, Board decision mailed 9/24/04, page 18.

The appellants in Appeal No. 2004-1732 also argued that the claimed nucleic acids could be used in "gene chips" or "DNA chips" to monitor gene expression. The appellants argued that "[s]uch "DNA chips" clearly have utility, as evidenced by hundreds of issued U.S. Patents. . . . Clearly, compositions that enhance the utility of such DNA gene chips, such as the presently claimed sequences encoding a testis specific Notch ligand, must in themselves be useful." Id.

The panel that decided Appeal No. 2004-1732 reviewed governing principles of law; addressed and rejected the appellants' arguments premised on DNA chips, gene

mapping, and exon splice junctions; and concluded that "Appellants' disclosure in th[at] case does not provide a specific benefit in currently available form, and therefore lacks the substantial utility required by 35 U.S.C. § 101." Id., page 27. Accordingly, the examiner's decision, rejecting all of the pending claims in Application No. 09/714,882, was affirmed.

As in Application No. 09/714,882, the broadest claim in this appeal (claim 4) is directed to "[a]n isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO:4." In this case, the claimed nucleic acid is disclosed to encode a protein that "share[s] structural similarity with animal kinases, including, but not limited to cell division control protein kinases, serine/ threonine protein kinases and membrane-associated guanylate kinases (MAGUKs)." Specification, pages 1-2. See also page 15: "In addition to serine/threonine kinases, the NHPs described in SEQ ID NO: 1-6 also share significant similarity to a range of additional kinase families such as NEK2 and NY-REN-55 as well as protein kinases from a range of phyla and species." The specification, however, does not disclose any biological activity of the polypeptide of SEQ ID NO:4, or any other basis for using the protein or DNA encoding it in a practical way. All of the claims stand rejected for lack of patentable utility. Examiner's Answer, page 3.

The Appeal Brief in this appeal includes essentially the same arguments that were made and rejected by the previous merits panel in Appeal No. 2004-1732.[3] For example, Appellants argue that:

[3] In addition to the arguments quoted above, Appellants cite a GenBank record that they characterize as showing a sequence that is "96.343% identical at the amino acid level over the entire length of the described sequence." Appeal Brief, page 4. Appellants argue that the utility of the claimed polynucleotides is supported by the characterization of the GenBank-recorded sequence as "Homo

• "Clearly, the present polynucleotide provides exquisite specificity in localizing the specific region of the human chromosome containing the gene encoding [sic, comprising?] the given polynucleotide. . . . The presently claimed polynucleotide sequence defines a biologically validated sequence that provides a unique and specific resource for mapping the genome." (Appeal Brief, pages 12-13);

• "The presently claimed polynucleotide sequence provides biologically validated empirical data (e.g., showing which sequences are transcribed, spliced, and polyadenylated) that specifically defines that portion of the corresponding genomic locus that actually encodes exon sequence." (id., page 13);

• "[T]he present nucleotide sequence would be an ideal, novel candidate for assessing NEK-1 kinase gene expression using, for example, DNA chips. . . . Such 'DNA chips' clearly have utility, as evidenced by hundreds of issued U.S. Patents. . . . Clearly, compositions that enhance the utility of such DNA chips, such as the presently claimed sequences encoding the human kinase NEK-1 must in themselves be useful." (id., pages 9-10);

On these facts, we require Appellants to explain why we should again address the same line of argument in this case: since the same arguments were considered and thoroughly addressed in Appeal No. 2004-1732, why would the previous panel's treatment of those arguments not be dispositive here? In particular, why should the facts and arguments set forth in the briefing of this appeal lead to a different conclusion than that reached by the panel in Appeal No. 2004-1732, which rejected the same arguments? We note that, according to PTO records, the appellants in Appeal No. 2004-1732 (Application No. 09/714,882) did not request rehearing under 37 CFR § 41.52, nor did they appeal the Board's decision, within two months from the date of the Board decision; the application has been abandoned.

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sapiens (Human) SERINE/THREONINE KINASE NEK-1." Id. We do not find this argument persuasive, because there is no evidence that the GenBank record was known to those in the art at the time the instant application was filed and the instant specification does not disclose that the claimed polynucleotides encode the serine/threonine protein kinase NEK-1. Thus, the post-filing evidence does not show that those skilled in the art would have recognized a patentable utility for the claimed invention at the time the application was filed.

Conclusion

In conclusion, we require Appellants to address the foregoing matters "consider[ed] to be of assistance in reaching a reasoned decision on the pending appeal." 37 CFR § 41.50(d). We caution, however, that this is not an invitation to expand on points raised in Appellants' brief or to rehash arguments already set forth in the brief. This is not an invitation to raise arguments or issues on appeal, or to collaterally attack the decision in Appeal No. 2004-1732. See 37 CFR § 41.37(c)(1)(vii) ("Any arguments or authorities not included in the brief or a reply brief filed pursuant to § 41.41 will be refused consideration by the Board, unless good cause is shown"). Appellants' response should be confined to the matters outlined above.

Time Period For Response

A period of one month from the date of this order is set for Appellants' response. This time is non-extendable.

Failure to respond in a timely manner will result in dismissal of the appeal.

37 CFR § 41.50(d)

William F. Smith)
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